

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A method for measuring quantitatively or qualitatively an analyte in a whole blood sample, comprising:

forming a reaction system by ~~adding to~~ mixing the whole blood sample with a whole blood treatment solution comprising detergent, and adding to the mixture of the whole blood sample and the whole blood treatment solution a first substance which is immobilized on a solid carrier and specifically binds to an analyte contained in the whole blood sample and a second substance which specifically binds to the analyte to allow the analyte to react with the first and second substances to form a complex of first substance-analyte-second substance, separating the complex, and

detecting the complex to measure quantitatively or qualitatively the analyte in the complex,

wherein said reaction system comprises the detergent in a concentration range of 0.5 to 5% so that hemolysis is prevented.

Claim 2 (original): The method according to claim 1, wherein the detergent is selected from the group consisting of polyoxyethylene sorbitan ester type detergents and sulfobetaine type detergents.

Claims 3-6 (canceled).

Claim 7 (currently amended): The method according to claim [[4]] 1, wherein the ratio of the whole blood sample and the whole blood treatment solution is in the range of 99:1 to 5:95.

Claim 8 (canceled).

Claim 9 (previously presented): The method according to claim 1, wherein the reaction system is formed by mixing the whole blood sample with a whole blood treatment solution comprising detergent, then adding the first substance to the mixture of the whole blood sample and the whole blood treatment solution, and then adding the second substance to the mixture of the whole blood sample, the whole blood treatment solution, and the first substance.

Claim 10 (previously presented): The method according to claim 1, wherein the second substance is labeled with a labeling substance.

Claim 11 (previously presented): The method according to claim 1, wherein the first and second substances which specifically bind to the analyte are an antigen or an antibody.

Claim 12 (withdrawn): A method for measuring an analyte in whole blood, which comprises:

(1) a dilution step of diluting whole blood by mixing the whole blood with a whole blood treatment solution;

(2) a first reaction step of adding a first substance carried by a solid carrier and specifically binding to the analyte to the diluted whole blood and allowing them to react to form a first reaction product in a reaction system;

(3) a first separation step of separating the first reaction product formed in the first reaction step from the reaction system;

(4) a second reaction step of adding a second substance specifically binding to the analyte to the separated first reaction product and allowing them to react to form a second reaction product in a reaction system;

(5) a second separation step of separating the second reaction product formed in the second reaction step from the reaction system; and

(6) a measurement step of measuring the separated second reaction product, wherein the whole blood treatment solution contains a sufficient amount of detergent that does not cause hemolysis, does not inhibit reactions of the analyte with the first and second substances, and can prevent influence on the reaction system of a component existing in the reaction system in each step when the solution is mixed with the whole blood.

Claim 13 (withdrawn): The method according to claim 12, wherein the second substance is labeled with a labeling substance.

Claim 14 (withdrawn): The method according to claim 13, wherein the first and second substances specifically binding to the analyte are antigen or antibody.

Claim 15 (currently amended): A reagent kit for measuring an analyte in a whole blood sample, which comprises a first substance which is immobilized on a solid carrier and specifically binds to the analyte, a second substance which specifically binds to the analyte,

and a whole blood treatment solution which comprises detergent ~~and is adjusted so that~~
~~detergent concentration is 0.5 to 5% when the solution is added to the whole blood sample,~~

wherein the whole blood sample is first mixed with the whole blood treatment
solution, and then the first and the second substances are added to the mixture of the whole
blood sample and the whole blood treatment solution to form a reaction system,

wherein said reaction system comprises the detergent in a concentration range of 0.5
to 5% so that hemolysis is prevented.

Claim 16 (canceled).

SUPPORT FOR THE AMENDMENTS

Applicant has amended Claim 1 for clarity and to change:

“forming a reaction system by adding to the whole blood sample a first substance which is immobilized on a solid carrier and specifically binds to an analyte contained in the whole blood sample and a second substance which specifically binds to the analyte to allow the analyte to react with the first and second substances to form a complex of first substance-analyte-second substance”

to

“forming a reaction system by ~~adding to~~ mixing the whole blood sample with a whole blood treatment solution comprising detergent, and adding to the mixture of the whole blood sample and the whole blood treatment solution a first substance which is immobilized on a solid carrier and specifically binds to an analyte contained in the whole blood sample and a second substance which specifically binds to the analyte to allow the analyte to react with the first and second substances to form a complex of first substance-analyte-second substance.”

Support for this amendment can be found in Claim 4, as previously presented.

Claim 15 has been amended to recite:

“wherein the whole blood sample is first mixed with the whole blood treatment solution, and then the first and the second substances are added to the mixture of the whole blood sample and the whole blood treatment solution to form a reaction system,

wherein said reaction system comprises the detergent in a concentration range of 0.5 to 5% so that hemolysis is prevented.”

Support for this amendment can be found in Claims 1, 4 and 15, as previously presented.

Claim 7 has been amended to properly depend from Claim 1. Support for amended Claim 7 can be found in the same claim, as originally filed.